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Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

Submitter Information

Esaote S.p.A. Via di Caciolle 15 Firenze, Italy 50127

Contact Person:

Allison Scott

317.228.8719

allison.scott@navigant.com

Date:

March 17, 2014

807.92(a)(2)

Devices

Common Name:

Ultrasound Imaging System

Trade Name:

7348 Ultrasound System

Classification Name(s):

Ultrasound Pulse Doppler Imaging System 892.1550

Ultrasound Pulse Echo Imaging System 892.1560 Transducer, Ultrasonic, Diagnostic 892.1570

Classification Number:

90IYN, 90IYO, 90ITX

807.92(a)(3)

Predicate Device(s)

Device	Owner	510(k)
7348	Esaote	K121384
7340	Esaote	K081794, K091009,
		K110688

Device Description

Model 7348 is a portable system equipped with a handle. The system size and weight allow it to be carried using its handle. The primary modes of operation are for both models: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), CW and PW Doppler, Color Flow Mapping (CFM) and Amplitude Doppler (AD). 7348 is equipped with a LCD color display where acquired images and advanced image features are shown. 7348 can drive Phased, Convex, Linear array and Doppler probes. Model 7348 has been designed to be powered by battery.

7348 has been previously cleared via k121384.

7348 Upgrade, defined herein, combine the cleared features of 7348 system with new software capabilities, listed below:

- 1. Managing of Tissue Velocity Mapping (TVM) and Tissue Velocity (TV) mode.
- 2. Managing of M-Mode with free positioning of the acquisition line (Compass M-Mode).
- Management of Stress Echo where detection of the occurrence of stress-induced wall motion abnormalities is derived through comparison of 2D loops, displaying wall motion at rest and during and after stress.
- 4. Management of Intima Media Thickness to automatically measure the thickness between the intima and the media on the image in real time.

The 7348 Upgrade is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use

Esaote's Model 7348 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdomninal, Laparoscopic and Other: Urologic. The 7348 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

The 7348 Upgrade employs the same fundamental technological characteristics as their predicate devices. The 7348 Upgrade model is substantially equivalent to Esaote 7348 model cleared via K121384, and to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.

 Clinical uses for which Esaote 7348 model, cleared by FDA via K121384, are designed are not changed by 7348 Upgrade, to be cleared via this submission.

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- Clinical uses for which Esaote 7348 Upgrade is designed are equivalent to those of Esaote 7348
 model cleared via K121384, and to Esaote 7340 model cleared by FDA via K081794, K091009,
 K110688.
- 7348 upgrade for managing Tissue Velocity Mapping (TVM) and Tissue Velocity (TV) mode is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing M-Mode with free positioning of the acquisition line (Compass M-Mode) is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing Stress Echo, where detection of the occurrence of stress-induced wall motion abnormalities is derived through comparison of 2D loops, displaying wall motion at rest and during or after stress, is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing Intima Media Thickness to automatically measure the thickness between the intima and the media on the image in real time, is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- Esaote 7348 Upgrade, 7348 and 7340 ultrasound models are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 7348 Upgrade, 7348 and 7340 ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

Summary of Non-Clinical Tests

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 6060 1-2-37
- NEMA UD-3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices
 on Diagnostic Ultrasound Equipment
- NEMA UD-2 Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The 7348 Upgrade is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

April 25, 2014

Esaote S.P.A.

% Allison Scott
Senior Consultant
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

Re: K140677

Trade/Device Name: 7348/MyLabSogno Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed Doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX Dated: March 17, 2014 Received: March 18, 2014

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the <u>MylabSogno</u>, as described in your premarket notification:

Transducer Model Number

PA230	<u>CA123</u>	<u>IOE323</u>
PA122	<u>CA431</u>	<u>LP323</u>
PA023	<u> 2 CW</u>	TEE132
LA435	<u>5 CW</u>	<u>TEE022</u>
LA522	<u>HFCW</u>	
LA523	<u>EC1123</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA). it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.goy/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

for

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.

510(k) Number (if known)	
K140677	•
Device Name	
AW/MyLabSogno dicelors for Use (Describe) ande's Model 7:148 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, ansecophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional a peripherical), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Introperative abdomniand, Laparoscopic and Other. Urologic in 7:48 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other atomical structures as well as peripheral nerve blocks in Musculoskeletal applications. Application Application Application	
Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Smal Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal	Il organ, Musculoskeletal (Conventional and minal, Laparoscopic and Other: Urologic, lacement of needles in vascular or other
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Turn of the (Solvet one or both as annicable)	
	Counter Use (21 CFR 801 Subpart C)
(X) Prescription Use (Part 2) OPR 601 Subpart D)	
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A	SEPARATE PAGE IF NEEDED.
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	
Smh.7)	·

7348 Upgrade

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations											
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tisaue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify		
Ophthalmic		<u> </u>						,				
Felal	P	P	P		P	P	P		P			
Alxlominal	P	P	P	P	P	P	P					
Intraoperative (Abdominal)	Р	Р	P	<u> </u>	17	P	P		P			
Intraoperative Neurological			<u> </u>									
Pediatric	Р	р	Р	P	Р	Р	P		P			
Small Organ [1]	P	P	P		Р	Ъ	Р		P			
Neonatal Cephalic	Р	Р	Р	Р	P	Р	Р	-	P			
Adult Cephalic	Р	Р	Р	Р	Р	Р	P		P			
Cardiac [2]	P	P	Р	Р	Р	P	9	N	P			
Transesophageal (Cardiac)	P	P	Р	P	Р	P	Р	N	, P			
Transesophageal (Non Cardiac)			 	 								
Transfectal	P	P	Р	<u> </u>	P	Р	Р		P			
Transvaginal	Р	P	P		P	Р	Р		. Р			
Transurethral												
Intravasculor	ļ											
Peripheral Vascular	Р	Р	la.	Р	P	Р	P		P			
Laparoscopic	P	P	P	<u> </u>	Р	Р	Р		Р			
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	Ρ.	P		P			
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		Р	P	P		4			
Other (Urological)	P	P	P	1	P	P	Р		P			

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Small Organs includes Breast, Thyroid and Testicles μ

[2]

Cardiac is Adult and Pediatric
Combined modes are: B + M + PW + CW + CFM + PD [3]

Previously cleared via k121384

7348 - PA230

						lode of Oper	tions			
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (apecify
Ophthalmic			 							1
Feral										
Atelominal	Р	Р	P	P	P	• Р	P		P	
Intraoperative (Abdominal)						1				
Intraoperative Neurological		-		<u> </u>						1
Pediatric						1				
Sntall Organ [1]			 							
Neonatol Cephalic			1	1						
Adult Cephalic	P	P	P	P	P	Р	P		Р	
Cardiac [2]	Р	P	P	Р	Р	P	P	N	P	
Transesophageal (Cardiac)										
Transesophagent (Non Cardine)			ļ — —							1
Transrectal										
Transvaginal										
Transurethral										
Intravescular										
Peripheral Vascular										
Laparoscopic						1				
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Uralogical)		[

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

7348 - PA122

					Ď	iode =(Open	tions			
Clinical Application	В	М	GWI	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specif
Ophthalmir			<u> </u>							
Fetal					- 					
Alxlominal								-		
intraoperative (Abdominal)									·	
intraoperative Neurological	1		<u> </u>							-
Pediatric	P	P	Р	P	P	Þ	P			-
Small Organ [1]	1									
Neonatal Cephalic	P	þ	Р	P	Р	P	P			
Adult Cephalic	1		 							
Cardiac [2]	P	P	Р	Р	P	Р	ų	N		
Transesophageal (Cardiac)	1	_								
Transemphageal (Non Cardiac)	1									
Transrecial										
Transvaginal										
Transurethral										
Intravascular	_		 			 	-			
Peripheral Vascular	P	Р	P	Р	Р	P	P			
L араговсоріс			 							
Musculo-skeletal Conventional (including Nerve Blocking)		 -	ļ ·							
Musculo-skeletal Superficial finctuding Nerve Blocking										
Other (Urological)			1							

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiae is Adult and Pediatric

[3] Combined modes are: B + M + PW + CW + CPM + PD

7348 - PA023

					M	ode of Opera	tions			
Clipical Application	B	М	1°WD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping fTVM)	Harmonic Imaging (TEI)	Other (specif
Ophthalmic	1		 							i
Frial .										
Abdominal			 							
Intraoperative (Abdominal)										
Intraoperative Neurological				1						
Pediatric	P	P	P	17	Р	P	P	-		
Smell Organ [1]			1							
Neonatal Cephalic	P	1,	P	P	P	p	P			
Adult Cephalic							l			
Cardino [2]	P	1,	P	P	ľ	P	P			
Fransesophageal (Cardiac)										ļ
Franscsophageal (Non Cardiac)	_		1							
Fransrectal	1 .		1		1		·			
Transvagina)			1							
[mn×vrethr#]						<u> </u>				
Intravascular	1				<u> </u>		_	<u> </u>	·	
eripheral Vascular	P	þ.	P	P	Р	Р	Р			
Lebetoscobic										
Musculo-skeletal Conventional including Nerve Blocking)										
Musculo-skeletal Superficial including Nerve Blocking)		•								
Other (Urological)			1			1				

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CW + CFM + PD

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

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7348 - LA435

					М	ode of Opera	tions			
Clinical Application	В	М	משיו	CWD	Color Doppler	Amplitude Doppler	Combined 3	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (apecify
Ophthalmic			1			<u> </u>				<u> </u>
Fetal			1							
Abdominal			1							
intraoperative (Abdominal)										
Intraoperative Neurological	1									
Pediatric	P	P	P		Р	Р	P		i i	Ĭ
Small Organ [1]	P	٠,	Р		ų	Р	Р			
Neonatal Cephalic										
Adult Cephalic						j				
Cardine [2]]
Transesophageal (Curdinc)			1 _							l
Transesophageal (Non Cardiae)										
Transrectal										
Transvegine!										
Transurethral	1									
Intravascular			 						1	
Peripheral Vascular	P	Р	P		μ	P	P			
Е мригожаріс				1	<u> </u>	Ì				
Muscuto-skeletal Conventional (including Nerve Blocking)	۹ ا	P	P		Р	Ρ.	Р	·		
Musculo-akeletal Superficial (including Nerve Blocking)	P	Р	P		P	Р	P			
Other (Urological)	 			<u> </u>					l	

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared vin k132231

| Small Organs includes Breast, Thyroid and Testicles |2| Cardine is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

7348 - LA522

	Mode of Operations												
Clinical Application	13	М	(IWF)	CWD	Color Doppler	Amplitude Dappier	Combined [3]	Tissue Velocity Mapping (I'VM)	Harmonu Imaging (TEI)	Other (sperif			
Ophthalmic	1	<u> </u>				 				i			
Felal	1	1	1										
Abdominal	1		1						<u> </u>				
Intraoperative (Abdominal)] -							
Intraoperative Neurological		1	1										
Pediatric	Р	Р	· P	i	P	P ·	P		t ^p	<u> </u>			
Smail Organ [1]	P	P	P	1	P	Р	P		P				
Neonatal Cephalic	1	 	1							1			
Adult Cephalic					,				I				
Cardine [2]	1		Ì	l									
Transesophageal (Cardine)					ļ	L·							
Transcsophageal (Non Cardiac)			1	i				-					
Transrectal													
Тгапяундіпні		1 "	1			1							
Transurethral		1											
Intravascular	,		1			<u> </u>							
Peripheral Vascular	P	Р	Р		P	Р	P		Р				
Loporoscopic		1		1		ľ							
Musculo-skeletal Conventional (including Nerve Blocking)													
Musculo-skeletal Superficial (including Nerve Blocking)								·					
Other (Urological)	<u> </u>	1				i "							

N: New indication; P. Previosuly cleared by FDA; E:Added unifer Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

(2) Cardiac is Adult and Pethntric

[3] Combined modes are: H + M + PW + CFM + PD

7348 - LA523

					Ì	dode of Oper	ations			
Clinical Application	В	М	PWD	CWD	Calor Doppler	Amplitude Doppler	Combined . 3	Tisaue Velocity Mapping	Harmonic Imaging (TEI)	Other (specify
Ophthalmic								111111		
Petal				,						
Abdominal	†									
Intraoperative (Alalomonal)			<u> </u>	 -		<u> </u>				
Intraoperative Neurological	 		1							
Pediatric	Р	P	P	ļ	I ^p	Р	Р		P	
Small Organ [1]	ч	Р	P		Р	Р	Р		P	
Neonatal Cephalic	 			<u> </u>	 	 				
Adult Cephalic										
Cardiac [2]	†		 							
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)				l		1				
Transfertal		************								
Transvaginal						<u> </u>				
Transurethral							·			
Intravascular			-		<u> </u>					
Peripheral Vascular	P	P	P	 	p	Р	Р		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blacking)	P	Р	P		P	P	P		Р	
Musculo-skeletal Superficial (including Nerve Blocking)	Þ	P	Р		Р	Р	₽		þ	
Other (Urological)	 		1							

N; New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k132466

[11] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B • M • PW • CFM • PD

7348 - CA123

					1	Vade of Oper	ations			
Clinical Application	19	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify
Ophthalmic			<u> </u>	<u> </u>						· ·
Fetal	-									
Abdominal	1			<u> </u>						·
Intraoperative (Abdominal)	+					 				
Intraoperative Neurological	1 1		<u> </u>			 				
Pediatrie	P	P	P		Р	P	P		P	
Small Organ [1]	P	Р	۱ ۲		· · · · · ·	TP TP	ь	·	þ	
Neonatal Cephalic	P	P	P		Р	P	Р		P	-
Adult Cephalic	1		 	 		 				
Cardine 2	P	ф	 			P	Ą			
Transesophageal (Cardiac)										-
Transesophageal (Non Cardiae)	1 1									
Transcetal	1 1		1			<u> </u>				
Transveginel										
Transurethral	1 1		<u> </u>			<u> </u>		-		
Intravascular	1									
Peripheral Vascular	P	P	Р	 	P	Р	Þ		P	
Гараговсоріс	1 1									
Musculo-skeletal Conventional (including Nerve Blocking)	P	Р -	P		۴	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	Р	P	p		Р	P	į+		ļ. 	
Other (Urological)										

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testerles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B * M * PW * CFM * PD

7348 - CA431

					M	lode of Opera	tions			
Clinical Application	н	М	iwb .	CWD	Cater Doppler	Amplitude Doppler	Combined (3)	Tissue Vélocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify
Ophthalmic	1.		<u> </u>							i
Fctal	þ	P	P		P	P	P		Р	
Abdominal	Р	Р	P	ļ	Р	Р	P		Р	
Intraoperative (Abdominal)			1							
Intraoperative Neurological						1				<u> </u>
Pediatric	Р	Р	P		Р	Р	P		Р	Ì
Small Organ [1]	<u> </u>		1 :			1				
Neonatal Cephalic			 	İ		İ				i
Adult Cephals:		_	1							I
Cardine [2]						1				
Transcsophageal (Cardiac)						ì				·
Transesophageal (Non Cardiac)			1							
Transrectal										Ī
Transvaginal			1							
fransurethral					<u> </u>					
Intravascular					<u> </u>					
Peripheral Vascular	Р	P	Р		P	P	P		Р.	
Laparoscopic			1]
Musculo-akeletal Conventional (including Nerve Blocking)	P	Р	P		Р	P	Р		Р	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		Р	P	P		P	
Other (Urological)	Ъ	þ	19		Р	Р	P		Р	

N: New indication; P: Previosity cleared by FDA; E:Added under Appendix E

Previously clented via k121384

(1)	Small Organs includes incust, mylosi and resurres
131	Combined to Advils and Hadinbeig

[2] Cardine is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

7348 - 2 CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows: Mode of Operations Color Amplitude Combined Other [specify] Clinical Application Tissur Harmenic Velocity Imaging (TEI) Doppier Doppler [3] Mapping (TVM) Ophthalmic Fetal Abdominal Intraoperative (Abdominal) Introoperative Neurological Pediatric Smell Organ [1] Neonatal Cephalic Adult Cephalic Cardiac [2] Transexophageal (Cardiac) Transesophageal (Non Cardiac) Transrectal [типаундіп»] Transurethrid Introvascular Peripheral Vascular

N: New indication; P: Previositly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

Musculo-akcletal Conventional fincluding Nerve Blockings Musculo-akcletal Superficial fincluding Nerve Blockings Other (Utological)

Сириголсоріс

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

7348 - 5 CW

	Mode of Operations												
Clinical Application	ß	М	PWD	CWD	Color Doppler	Amphiude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (apecify)			
Ophthalmic	<u> </u>									<u> </u>			
Fetal													
Abdominal	1												
Intraoperative (Abdominal)													
Intraoperative Neurological	<u> </u>					1			·	<u> </u>			
Pediatric					 -				ĺ				
Small Organ [1]	1				<u> </u>								
Neonatal Cephalic		······	1		 								
Adult Cephalic													
Cardiac [2]					<u> </u>								
Transesophageal (Cardiac)	1	 				<u> </u>							
Transcapphageal (Non Cardiac)		· · · · ·	1		1								
Transfectal			 -										
Fransvaginal					<u> </u>								
Transurethral		 			<u> </u>								
Intravascular			<u> </u>							1			
Peripheral Vasculor		 		P	1								
Laparoscopic		1	 			1		<u> </u>					
Musculo-skeletal Conventional (including Nerve Hlocking)													
Musculo-skeletal Superficial (including Nerve Blocking)													
Other (Urological)		<u> </u>											

N: New indication; P: Previosily cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

7348 - HFCW

Clinical Application	Mode of Operations											
	В	М	PWI)	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping	Harmonic Imaging (TEI)	Other (specify)		
Ophthalmic												
Petal	<u> </u>											
Abdominal												
Intraoperative [Abdominal]						T						
Intraoperative Neurological						<u> </u>			1			
Pediatric			1									
Small Organ [1]												
Neonatal Cephalic												
Adult Cephalic	-t		1		İ	, .						
Cardine [2]												
Transesophageal (Cardiac)	T		1									
Transesophageal (Non Cardiae)	T				1	-						
Transfectal	1		1							i		
Transvaginal												
Transurethral												
Intravascular	1											
Peripheral Vascular	Ì			P	·							
Laparoscopic												
Musculo-skeletal Conventional (including Nerve Blocking)												
Musculo-skeletal Superficial (including Nerve Blocking)												
Other (Urological)			1									

N: New indication; P: Previously cleared by FDA: E:Added under Appendix E

Previously cleared via k110688

[1] Small Organs includes Breust, Thyruid and Testicles

[2] Cardiac is Adult and Pediatric

7348 - EC1123

	Mode of Operations												
Clinical Application	В	М	РWO	CWD	Colur Doppler	Amplitude Doppler	Combined (3)	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)			
Ophthalmic	<u> </u>		<u> </u>										
Fetal	P	P	P		P	P	F F		P	-			
Abdominal	<u> </u>												
Intraoperative (Abdominal)			1			İ							
Intraoperative Neurological													
Pedintric			 	† ·									
Small Organ [1]									-				
Neonatal Cephalic							1						
Adult Crphalic													
Cardon [2]					· · · · · · · · · · · · · · · · · · ·								
Transesophageal (Cardiac)				<u> </u>									
Transesophageal (Non Cardine)													
Transrectal	l,	r	Р		P	P	P		р				
Transvaginal	Р	Р	P		P	Р	P		P				
Transurethral	1												
Intravascular				 		 							
Periphera) Vascular	1			 									
Laparoscopic	 			-									
Musculo-skeletal Conventional (including Nerve Blocking)	1												
Musculo-skeletal Superficial (including Nerve Blocking)													
Other (Urological)	P	P	P		P	P	P		P	1			

N: New indication; P: Previosally cleared by FDA; E:Added under Appendix E

Previously cleared via k132231

Small Organs includes Breast, Thyroid and Testicles $\mathbf{p}_{\mathbf{i}}$ Cardine is Adult and Pediatric

[2] [3] Combined modes are: B + M + PW + CFM + PD

7348 - IOE323

	Mode of Operations											
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined 3	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify		
Ophthalmic												
Fetal												
Abdominal	Р	Р	Р		P	Р	Р					
Intraoperative (Abdominal)	P	P	Ъ		P	P	Р					
intraoperative Neurological												
Pediatric	Р	P	P		p	P	Р					
Small Organ [1]	P	Р	P		P	P	P					
Neonatal Cephalic	 					 						
Aduli Cephalic			<u> </u>					-				
Cardiac [2]	 											
Transesophagent (Cardiae)	 											
Transesophageal (Non Cardiac)	 				_							
Transfectal												
Transvagmal												
Transurethral					-							
Intravascular	1	, .				1						
Peripheral Vascular	P .	Р	P		P	Р	P			,		
Lupuroscopic	 	· · ·			 -	 						
Musculo-skeletal Conventional fineluding Nerve (Hocking)	P	Р.	Р		Р	P	P					
Musculo-skeletal Superficial (including Nerve Blocking)	P	þ	P.		P	P	Р			-		
Other (Urological)	1											

N: New indication; P. Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

mi.	Small Organs includes Breast, Thyroid and Testicles
1.1	Silini Cignia alcidaca Bician, ilijiola tam remiera

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

7348 - LP323

		<u>Mode of Operation</u> ≥											
Cibical Application	В	М	PWD	CWD	Color Duppler	Amplitude Doppler	Combined [3]	Tisaue Velocity Mopping (TVM)	Hermonic Imaging (TEI)	Other (specify)			
Ophthalmic													
FetaJ	1												
Andominal	9	P	Р		ľ	P	P	<u> </u>					
Intraoperative (Abdominal)													
Intraoperative Neurological													
Pedintno													
Small Organ [1]													
Neonatal Cephalic	 					1							
Adult Cephalic													
Cardiac (2)	<u> </u>				···········	 							
Transcrophageal (Cardiac)	- · · · · ·												
Trunsesophageal (Non Cardiac)													
Transrectal													
Transvaginal		·····											
Transurethral						ļ <u> </u>							
intravascular	<u> </u>												
Peripheral Vascular													
Імратовсоріг	P	Р	Р		P	P	P						
Musculo-skeleral Conventional lincluding Nerve Blocking)													
Musculo-skeletal Superficial (including Nerve Blocking)		1											
Other (Urological)	1	<u> </u>			i	1		i					

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

Small Organs includes Breast, Thyroid and Testicles [1] [2] [3] Cardiac is Adult and Pediatric

Combined modes are: B + M + PW -> CFM + PD -

7348 - TEE132

1	Mode of Operations											
Clinical Application	В	М	PWD	CWD	Calor . Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping	Harmonic Imaging (TEI)	Other (specif)		
Ophthalmic				I								
Feial			I	,		I						
Abdominal			1	I								
Intreoperative (Abdominal)				1		Ì				1		
Intraoperative Neurological				1	-							
Pedratric			1									
Small Organ [1]												
Neonatal Cephalic						1						
Adult Cephalic			1									
Cardisc [2]										I		
Transesophageal (Cardine)	P	Р	Р	Р	P	P	P	22	Р			
Transesophageal (Non Cardine)												
Transrectal												
Transveginal												
Transurethrul				1					ľ – – – – – – – – – – – – – – – – – – –			
Introvascular			1			1						
Peripheral Vascular			<u> </u>				<u> </u>					
Laparoscopic			<u> </u>	1	<u> </u>		1					
Musculo-skeletal Conventional tincluding Nerve Blocking												
Musculo-skeletal Superficial (including Nerve Blocking)			1									
Other (Uralogical)			1	T		Ţ.						

N: New indication; I': Previously cleared by PDA; E:Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breust, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: Ft + M + PW + CW + CFM + PD

7348 - TEE022

	Mode of Operations											
lipical Application	В	м	PWD	CWD	Color Duppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping	Harmonic Imaging (TEI)	Other (specify		
Ophthalmic										L		
Fetal				1.		1				L		
Abdominal			l									
Intraoperative (Abdominal)						1						
Intraoperative Neurological												
Pediatric		<u> </u>	1			Ì						
Small Organ [1]		1										
Neonatal Cephalic		1	1							T		
Adult Cephalic		<u> </u>	· · · · · · ·	†								
Cardiac [2]			1									
Transesophageal (Cardiae)	Р	P	P	ľ	P	P	P	5	Р			
Transesophageal (Non Cardiac)										i		
Transcectal												
Transcaginal		1										
Transurethral			1									
Intravascular										I		
Peripheral Vascular			1									
Laparoscopie			1									
Musculo-skeletal Conventional (including Nerve Blocking)												
Musculo-skeletal Superficial (including Nerve Blocking)												
Other (Urological)		1	\vdash						I			

N: New indication: P: Previosuly cleared by FDA; E:Added under Appendix E

Previously cleared via k121384

[1]	Small Organs includes Breast, Thyroid and Testicles
[2]	Cardiac is Adult and Pediatric
[3]	Combined modes are: ft + M + PW + CW + CFM + PD